DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

SRMC Company, LTD
% Ms. Priscilla Chung
LK Consulting Group USA Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K141046
Trade/Device Name: MiDi-SRS
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG and GEX
Dated: November 26, 2014
Received: December 2, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141046

Device Name
MiDi-SRS

Indications for Use *(Describe)*
MiDi-SRS is intended for use in dermatological procedures requiring the coagulation of soft tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(K141046)

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___11/26/2014___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	MiDi-SRS
Common Name:	Laser Surgical Unit
Classification Name:	Powered Laser Surgical Instrument
Classification:	Class II, 21 CFR 878.4810
Classification Product Code:	ONG

4. Predicate Device:

SellaS by Dinona Company, Ltd. (K080382)

5. Device Description:

MiDi-SRS is designed to provide laser energy (1550nm) for use in a variety of dermatology and general surgery procedures. The product consists of main body, a tablet PC, a foot switch, an interlock switch and a key switch. The device fires a 1550nm Er- glass Fiber laser beam which is

then split into a number of microscopic beams, producing tiny dot, or pixel-like treatment zones within the selected target area of the skin, leaving the other zones within it perfectly intact.

6. Intended Use:

MiDi-SRS is intended for use in dermatological procedures requiring the coagulation of soft tissue.

7. Performance Data(Non-Clinical):

Bench tests were performed according to EN 60601-2-22, 60601-1 and 60601-1-2 to evaluate its safety and EMC. All the test results met pre-set criteria and support substantial equivalence to the predicate devices.

In vivo animal testing using porcine models was also conducted to obtain histological data of values for depth and zone of ablation and thermal damage immediately post treatment; 3-5 days post treatment; and 10-14 days post treatment. The test results are as below and supports that the subject device would perform as well as the predicate device.

Group / Excision days		Microscopic treatment zones (MTZs)			
		Measurement value (μm)			
		Measured width (S.D.)	Measured depth (S.D.)	Thermal zone: lateral	Thermal zone: depth
G1	10mJ	17	17	151	205
0	20mJ	33	34	226	290
	30mJ	29	36	277	325
G2	10mJ	17	64	19	57
3	20mJ	13	16	42	132
	30mJ	3	10	32	104
G3	10mJ	0	0	0	0
10	20mJ	0	0	0	0
	30mJ	0	0	0	0
G4	10mJ	0	0	0	0
15	20mJ	0	0	0	0
	30mJ	0	0	0	0

8. Substantial Equivalence

The MiDi-SRS is substantially equivalent to the predicate device in terms of indication for use and technology based on technical characteristics. The two devices are similar in the following

characteristics: intended use, spot size, wave length, aiming beam, power output, energy range, output mode, laser type, and beam mode. The major difference is in the user interface, however, the SW validation report provided in the submission supports that the touch screen tablet SW of the Midi-SRS is substantially equivalent to the predicate device in effectiveness.

9. Conclusion:

Based on the substantial equivalence discussion and testing results, SRMC CO., LTD concludes that the MiDi-SRS is substantially equivalent to the predicate devices in safety and effectiveness.